

c8 the lycopene additive has a soluble solids concentration below 5° Bx.

REMARKS

Applicants first wish to thank the examiner for the courtesies extended during the personal interview held in the examiner's office on September 4, 2001, at which were present the examiner, Dr. Mushkin and undersigned. While a full agreement was not conclusively reached, considerable progress was made as indicated in the last sentence of the "Interview Summary".

The present reply, including the amendments presented above, are in response to the Office Action of June 26, 2001, as well as the various points discussed during the lengthy interview of September 5, 2001. The claims in the application are now claims 1-14, 23-28 and 41-45. Applicants' claims meet the requirements of §112, define novel and unobvious subject matter under Sections 102 and 103 and should be allowed. Accordingly, applicants respectfully request favorable consideration and allowance.

In general, the claims as amended above are consistent with what was discussed during the aforementioned interview.

As also discussed during the interview, applicants offer to cancel claim 44 if claim 1 is found to be allowable.

New claim 45 is submitted as a replacement claim for earlier cancelled claims 15 and 16, which were non-statutory but included within the elected subject matter. Examiner Sherrer during the interview indicated that such a new claim would be considered, consistent with claims 15 and 16 having been classified with elected Group I.

Briefly, applicants wish to emphasize two points at the outset. The present composition is novel and unobvious in that it has a very low Brix with a very high lycopene content. Commercial tomato based products, with the exception of tomato juice, have a very high Brix; tomato juice, while having a relatively low Brix, also has a much lower lycopene content, i.e. about 60 ppm, than the composition of the present invention.

Second, in the manufacture of tomato based products, the tomato is usually subjected to two unit operations which cause extensive damage to the chromoplasts, these two operations being (1) the application of heat, and (2) the application of intense mechanical activity. Maintaining a high percentage of intact chromoplasts according to the present invention is accomplished by avoiding or minimizing these unit operations. Thus, in accordance with the present invention, the solids are separated from the liquid simply by centrifugation.

Claims 1-14, 23-28 and 44 have been rejected under the first paragraph of Section 112. This rejection is respectfully traversed.

Support for the concentration of chromoplasts as recited in applicants' claims is found in line 2 on page 9 of applicants' specification. It will be understood that as the lycopene is encapsulated in the chromoplasts¹, the concentration given of 500 to 3,000 ppm is for the lycopene-encapsulated material, i.e. the "chromoplast particles encapsulating crystalline lycopene" as claimed.

Applicants respectfully request withdrawal of this rejection.

Claims 1-14, 23-28 and 41-48 have been rejected under the first paragraph of §112 as based on a specification which is not enabling as regards extraction of the chromoplasts from the fruit without causing substantial mechanical breakage or destruction of the chromoplasts (e.g. note applicants' specification at page 7, lines 8-10). This rejection is respectfully traversed.

As pointed out in applicants' specification and as explained during the aforementioned lengthy interview, centrifugation is known in the art to be a gentle separation

¹ As indicated in applicants' specification, not all of the chromoplasts are necessarily intact.

process. This is what is disclosed in applicants' specification (see page 11, lines 8 and 19, page 13, lines 5 and 13). This separation process is also shown in the examples, attention being invited to the fifth line of Example 1, the second line of Example 2 and the fourth line of Example 3. That simple centrifugation works is shown by the results which the applicants obtained.

Certainly those skilled in the present art would have no trouble practicing applicants' invention based on their common knowledge coupled with applicants' disclosure as noted above. Indeed, applicants believe that there would be no experimentation necessary at all. However, if any experimentation were necessary, it would at most be routine experimentation which is well accepted to be permissible under 35 U.S.C. 112. Thus, applicants respectfully submit that little or no experimentation would be necessary, taking into account the fact that centrifugation is known in the art to be gentle, coupled with applicants' examples and the results obtained.

Applicants respectfully note that insofar as the prior art is concerned, tomato-based products in particular are always heated substantially. Such heating particularly when employed with mechanical separation, destroys the chromoplasts.

Withdrawal of the rejection based on the first paragraph of §112 is fully justified, and is respectfully requested.

Claims 1-14, 23-28 and 41-44 have been rejected under the second paragraph of §112. This rejection is respectfully traversed.

While applicants respectfully but strongly disagree that terms such as "substantially", "partially", "flavor" and "high" somehow render claims indefinite, the claims as rewritten above no longer use the terms "substantially" and "partially", but instead are in accordance with the terminology discussed in the aforementioned interview.

So that the record will be clear, however, applicants respectfully note MPEP 2173.05(b) which specifically deals with the words "substantially" and "substantial", citing case law authority to the effect that such terminology is perfectly acceptable. Indeed, the Supreme Court of the United States, in a ruling which has not been overturned by any later Supreme Court decision or by statute, so held in the famous *Eibel* case, *Eibel Process v. Minnesota & Ontario Paper*, 261 US 45. In the very same case, the Supreme Court approved the term "high".

Also please see *Charvat v. Commissioner*, 182 USPQ 77, 585, where "high concentration" was found to be

acceptable. In *Ex parte Romentschuk*, 188 USPQ 542, the terminology "small amount" was found to be acceptable. The critical terminology in applicants' claims was not indefinite, because it would be well understood by those skilled in the art upon reading applicants' specification. Nevertheless, as indicated above, "substantially" and "partially" are no longer recited.

As regards the term "flavor", a quick search in the PTO website for claims in US patents issued since 1996 showed a total of 947 patents containing claims which include the word "flavor". Some of the more recent ones are USP 6,306,451; claim 7 of USP 6,306,449; claim 12 of USP 6,306,445; claim 1 of USP 6,306,372; claims 3-8 of USP 6,303,566; claim 4 of USP 6,303,173; USP 6,303,172; claim 1 of USP 6,299,925; USP 6,294,579; USP 6,287,618; and many, many, many others.

When it is taken into account that the U.S. Patent and Trademark Office has issued almost 1,000 patents in the past 5 years which contain claims including the word "flavor", it cannot be validly said that such a term is indefinite. Attention is respectfully invited to *Ex parte Brian et al*, 118 USPQ 242, 245 (1958) where the Board stated in part as follows:

..., Appellants have referred to numerous patents dealing with the subject matter

involved in the present case, which have been allowed on the basis of claims [using particular] characteristics... Since the claims under consideration are similar to those in the patents, we do not feel disposed to reject them and thus upset such a long established practice in the particular art under consideration. Accordingly, we will not sustain the rejection...

Accordingly, claim 4 is not indefinite simply because it included the term "flavor", which in any event, has now been deleted as unnecessary.

As regards claim 5, it has already been noted above that the term "high" has been approved by the United States Supreme Court, and in other cases, noting the citations above. Applicants submit that "high lycopene content tomatoes" are well known.

As regards claim 10, the phrase "water soluble flavors" has been deleted as unnecessary.

As regards claim 12, the Examiner is correct and the claim has been appropriately amended.

As regards claim 25, the comments made above with respect to claim 4 are fully applicable. Nevertheless, as the term "tomato flavor" is unnecessary in claim 25, such term has been deleted.

Applicants respectfully request withdrawal of the rejection based on the second paragraph of 35 USC 112.

For the record, applicants respectfully maintain that their claims as previously submitted were not indefinite, but at most may have been objectionable only as to form. The amendments presented are largely of a cosmetic or formal nature, i.e. made to place the claims in better form consistent with U.S. practice. The amendments are not "narrowing" amendments because the meaning of the claims has not been changed. Indeed, in some cases the amendments may even be considered "broadening" amendments. Applicants maintain that the scope of the claims has not been reduced; no limitations have been added and none are intended.

Claims 1-14, 23-25 and 28 have been rejected as anticipated by Graves '095. This rejection is respectfully traversed.

As pointed out during the aforementioned interview, after separating the carotenoid-containing natural source into a carotenoid-containing liquid fraction and a pulp fraction (see column 2, lines 54 et seq.), Graves **works with the liquid fraction**, contrary to the present invention, i.e. the Graves second step is

(ii) treating the carotenoid-containing **liquid** fraction with a carotenoid precipitation agent including calcium chloride, calcium hydroxide, calcium lactate or calcium gluconate, so as to fractionate the **liquid** fraction into a carotenoid-enriched solid precipitate portion and a

carotenoid-depleted liquid portion,...
(emphasis added)

Then, as previously indicated, Graves further teaches away from the present invention by emphasizing the necessity of disruption of the cell structure of the carotenoid source (column 3, lines 16-19).

The present invention is clearly fundamentally different from Graves: in the present invention, after gentle separation of the solids from the liquid by centrifugation, applicants obtain the chromoplast encapsulated lycopene from the solid fraction, and avoid disruption of the chromoplast as much as is reasonably possible.

Withdrawal of the rejection is clearly in order, and is respectfully requested.

Claims 14 and 41-43 have been rejected as anticipated under §102 by Tonnuci, the reference on page 6, paragraphs 20 and 21 of the Office Action to "Tannic et al" being a typographical error as explained by the Examiner. This rejection is respectfully traversed.

As discussed during the interview, Tonnuci relates to commercial tomato-based products such as soups, canned tomatoes, ketchup, spaghetti sauce, tomato paste, tomato puree, tomato juice and tomato sauce. The rejection focuses

on Table 3 which shows that tomato paste² has a lycopene content (according to the rejection) of around 550 ppm.

As pointed out during the aforementioned interview, all of the Tonnuci products are commercial products taken so-called "off the shelf". All of these commercial products are subjected to substantial heat during their preparation.

Therefore, the commercial products as disclosed by Tonnuci cannot meet applicants' claims wherein the chromoplasts encapsulate the lycopene, it being understood that the chromoplasts in the present invention are largely or even substantially intact.

In paragraph 57 of the final Action, the PTO indicates that it need not give any weight to so-called process limitations. Applicant does not see that there are any process limitations in any of these claims, and accordingly applicant does not understand the point raised in paragraph 57. The criticized claims are directed to a particular type of product, and the language in question defines what the product is. Attention is respectfully

² The final Action also states on page 14, paragraph 56 that it is "well known that tomato juices will have Brix values of around 5, even less than 5." Tomato juices usually have a Brix value somewhat greater than 5, i.e. about 7. Regardless, no tomato juice would correspond to applicants' claims because the chromoplast particles will have largely been destroyed by heating to make the canned tomato juice safe, and tomato juice will not contain 500 to 3,000 ppm of chromoplast particles as claimed, i.e. only about 60 ppm.

invited to *In re Bulloch et al* 203 USPQ 171, 174 (CCPA 1979), where the court stated as follows:

Although the claims are not drafted in the usual form of use or method claims, we view the "concentrates" (containing alcoholates of AEMT orthophosphates) of the claims as limited to "stable color developers." The introductory claim language "stable color developer concentrate" is more than a mere statement of purpose; and that language is essential to particularly point out the invention defined by the claims. See *Kropa v. Robie*, 38 CCPA 858, 187 F.2d 150, 88 USPQ 478 (1951); cf. *In re Higbee*, 527 F.2d 1405, 188 USPQ 488 (CCPA 1976).

Also see *In re Steppan et al*, 156 USPQ 143, 147; *In re Garnero*, 162 USPQ 221, 223.

Applicants respectfully request withdrawal of the rejection based on *Tonnuci*.

Claims 1-3, 5 and 23 have been rejected as anticipated under §102 by *Iwatsuki*. This rejection is respectfully traversed.

Iwatsuki was discussed at some length during the aforementioned interview, and it was agreed that *Iwatsuki* is very difficult (if not impossible) to understand. Fig. 3 is unclear, and it is unclear exactly what *Iwatsuki et al* did and obtained. It seems that there are two possibilities, i.e. *Iwatsuki et al* either obtained a product containing a maximum of 70 ppm of chromoplast particles as per Fig. 3, in which case *Iwatsuki* clearly would not meet applicants' claims; or

Iwatsuki et al may have totally isolated the chromoplasts as previously argued³, in which case again Iwatsuki would not meet applicants' claims.

Applicants respectfully especially note the first paragraph under the heading "results and discussion" appearing at page 764 of the publication in which Iwatsuki appears. This paragraph indicates that the Iwatsuki method involved "two principle steps: Sephadex G-25 gel filtration of tissue homogenates followed by Percoll density gradient centrifugation." This suggests that Iwatsuki was working on a liquid fraction rather than isolating chromoplasts from any solid fraction.

The above noted paragraph adds, "Passing the tissue homogenates through the Sephadex G-25 columns prevented the homogenates from gelling. The homogenates from ripe fruits gelled quickly when they were left standing without the gel filtration." This is completely mystifying. The Iwatsuki description makes no sense to applicants and applicants respectfully maintain that Iwatsuki is not enabling, and therefore does not anticipate applicants' claims.

³ With reference to Paragraph 55 on page 14, the PTO has misunderstood the arguments of the last Reply. What applicants argued in the last Reply was that Iwatsuki may be directed to **isolation** of the chromoplasts, i.e. does not relate to a composition as claimed containing 500-3,000 ppm of chromoplast particles. However, Iwatsuki appears to be so unclear as to be non-enabling.

Applicants respectfully request withdrawal of the rejection.

Claims 8, 9 and 11 have been rejected as anticipated under §102 by Dale. This rejection is respectfully traversed.

As is clear from the abstract of Dale, the Dale "process alternatives" all involve substantial heating, which results in destruction of the chromoplasts. On the first page, second column under the heading "MATERIALS & METHODS", it is indicated that the chopped tomatoes were heated to 90°C. Such a "hot break" is called for in all five systems of Dale as shown on the following page, and this is followed by triple effect evaporation. All this use of heat is contrary to the present invention.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-3 and 5-7 have been rejected as anticipated by Brumlick. This rejection is respectfully traversed.

Brumlick, similar to most of the other citations, is interested in a commercial way of making food products including tomato-based or tomato flavored foods or concentrates. In every case as shown in Fig. 1 and described at column 2, lines 57-61, the vegetable juice, separated from the vegetable solids "is passed through one or more filters in

a filtering step 15 followed by evaporating or distilling operations 16 in which a substantial amount of the liquid or water is removed to provide a thick, viscous residue 17." (emphasis added).

Here again, as in Graves discussed above, Brumlick is working with the liquid fraction rather than the solid fraction. Then, to make Brumlick even more distinct from the present invention, the liquid is subjected to high heat which will inevitably destroy the chromoplasts. Indeed, the resultant thick, viscous residue 17, obtained after distilling off the water, is then subjected to even more heat in a radiation step 21 "which is sufficient to toast the material..." (column 3, line 4).

Clearly Brumlick anticipates neither applicants' process nor applicants' product. Accordingly, applicants respectfully request withdrawal of the rejection.

Claims 1-3, 5, 6, 13 and 14 have been rejected as anticipated by Szabo. This rejection is respectfully traversed.

Szabo relates to the manufacture of tomato puree. As indicated above, in the manufacture of such commercial products, the tomato material is inevitably heated to a relatively high temperature which inevitably results in the destruction of the chromoplasts.

Exactly what Szabo does is somewhat unclear. However, it appears that after breaking, Szabo obtains a tomato juice (see Fig. 1). Such juice, containing tomato colloids having negative electric characteristics (column 1, lines 45 et seq.) is then subjected to coagulation, preferably using calcium ions.

Next, a "considerable parts of the serum can be decanted and evaporated." (column 2, lines 14-15). Presumably evaporation involves substantial heat. Evaporation is also mentioned at column 2, lines 19-30, and it is unclear whether this is the same evaporation or a further evaporation. What is obtained eventually is a concentrated serum which smells of tomato (column 2, lines 37-38), clearly suggesting that the chromoplasts have been destroyed as is in any event inevitable due to the substantial heating applied. Also see column 3, lines 5-10 in this regard.

The resultant product of Szabo is a tomato puree which "has an attractive appearance, smells like tomato [and can be used to make "dishes"] which have taste and character similar to those made with the traditional tomato purees." In the present invention, the tomato smell and taste are largely eliminated. Neither the process nor the product of Szabo correspond to the claimed subject matter.

Applicants respectfully request withdrawal of the rejection.

Claims 1-5 and 14 have been rejected as anticipated by Bradley. This rejection is respectfully traversed.

As with most of the other references relied upon, Bradley also is concerned with the manufacture of a tomato based food product such as juice, soup, sauces, paste (column 5, lines 12-15). Bradley is particularly interested in a particular part of the overall process involving separating a tomato macerate to a reduced insoluble solids pulp fraction and an insoluble solids-enhanced pulp fraction. At the very beginning, after chopping the fresh tomatoes, they "are heated to inactivate enzymes" (column 3, lines 6 and 7). If the tomatoes are macerated using the hot-break method, they are heated to 60-100°C, preferably at least 85°C (column 3, lines 25-30).

Bradley appears to favor the hot-break⁴ procedure, and in this regard suggests higher temperatures for better consistencies, noting column 5, lines 7 and 8:

Generally higher break temperatures yield higher consistencies for both fractions.

In the illustrated embodiment, hot-breaking is disclosed

⁴ But even the cold-break procedure normally involves substantial heating, noting the Lang reference discussed below.

noting the hot-break tanks 110 and 120 (see column 8, lines 3 etc.). In the sole example (column 9), a hot-break tomato macerate is used.

Bradley also discusses the aforementioned Szabo patent and basically confirms applicants' position at column 5, lines 44-50 as follows:

Secondly, the mechanical separation procedure of the prior art [Szabo], i.e. high speed centrifugal separation, unavoidably **degrades** the cellular structure of the tomato macerate,... This **degradation** unavoidably impairs the ultimate consistency obtained in subsequently obtained tomato products. (emphasis added)

While the separation practiced by Bradley is apparently less vigorous than that practiced by Szabo, Bradley does not avoid the use of heat.

In the end, Bradley does not and cannot obtain what is claimed, namely

a coloring material in the red color range, comprising

chromoplast particles encapsulating crystalline lycopene as the color-imparting agent,

said chromoplast particles being particles separated from a fruit which contained them,

wherein the coloring material comprises from 500 to 3000 ppm of said chromoplast particles encapsulating crystalline lycopene, and

wherein the coloring material has a soluble solids concentration below 5° Bx.

Applicants respectfully request withdrawal of the rejection.

Claims 1-5, 7, 13 and 14 have been rejected as anticipated by Lang. This rejection is respectfully traversed.

Lang suffers from many of the deficiencies of the references already discussed above in the manufacture of a tomato based product for storage and consumption. Heating is unquestionably an aspect of the Lang process, and interestingly Lang defines even the "cold break" method as involving temperatures of 70-75°C (column 2, lines 3-9) with tomatoes processed according to the "hot break" method being heated to 95-100°C. In Lang, the tomato slices are heated to a temperature of at least 65°C (abstract line 5; column 2, lines 28-31), and more preferably at least 75°C (column 2, lines 64). Apparently the temperature must be sufficiently high to denature the polygalactonase in the tomatoes (column 2, lines 3 and 4; lines 67 and 68). In the illustrated embodiment, the tomato serum is heated to approximately 95°C (column 4, lines 24-25). As pointed out above, the processing including such heating inevitably ruptures the chromoplast walls.

As with the other prior art documents discussed above, Lang does not and cannot obtain the claimed subject matter including chromoplast particles encapsulating crystalline lycopene, wherein the coloring material comprises from 500-3,000 ppm of the chromoplast particles, and wherein the coloring material has a soluble solids concentration below 5 degrees Brix.

Applicants respectfully request withdrawal of the rejection.

Claims 26 and 27 have been rejected as obvious under §103 from Graves in view Horn. This rejection is respectfully traversed.

Graves has been discussed above where it has been pointed out how applicants' claims define over Graves. Horn has not been cited to make up for what applicants have pointed out that Graves does not have. Therefore, even if the combination were obvious (not conceded by applicants), the resultant combination would not correspond to what is claimed.

Applicants respectfully request withdrawal of the rejection.

Claims 1-5, 7, 13 and 14 have been rejected as obvious from Lang in view Brumlick. This rejection is respectfully traversed.

The ways in which the present invention defines over Lang have been discussed above. Brumlick does not make up for these differences and has not been cited to do so. Therefore, even if the proposed combination were obvious, not admitted by applicants, the resultant combination would not correspond to the claimed subject matter.

Applicants respectfully request withdrawal of this rejection.

Claims 1-14 and 24-28 have been rejected as obvious from Tonnuci (again, reference to "Tannic" is a typographical error in paragraphs 47 and 48 of the Official Action) in view of Dale. This rejection is respectfully traversed.

Both Tonnuci and Dale have been discussed above, and both relate to similar subject matter, i.e. commercial tomato based products which have been subjected to substantial heat during their manufacture. No possible combination of these documents could result in applicants' claimed subject matter, even if the combination were obvious.

Applicants respectfully request withdrawal of this rejection.

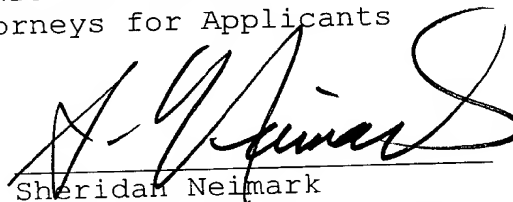
None of the references even hint at the present invention. Applicants have shown that heat is invariably used in the manufacture of tomato based food products, and that

heat disrupts the chromoplast shell exposing the crystalline lycopene to easy degradation. The present invention has solved problems which existed in the prior art, thereby solving a long felt need, and defines novel and unobvious subject matter warranting allowance. Applicants accordingly request favorable reconsideration and allowance.

Respectfully submitted,

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Version with Markings to Show Changes Made

1. (Twice Amended) A coloring material in the red color range comprising, ~~as the color-imparting agent,~~
chromoplast particles encapsulating crystalline lycopene as the color-imparting agent,

said chromoplast particles being particles separated from a fruit which contained them, and

wherein the coloring material comprises from 500 to 3000 ppm of said chromoplast particles encapsulating crystalline lycopene, ~~and wherein the chromoplast particles are substantially intact, and~~

wherein the coloring material has a soluble solids concentration below 5° Bx.

4. (Amended) A coloring material according to claim 1, which has been water-washed ~~to remove flavors.~~

8. (Twice Amended) A process for preparing a coloring material comprising as a color-imparting agent chromoplast particles containing crystalline lycopene, comprising:

a) selecting and pre-treating a lycopene-containing fruit by cleaning it;

b) breaking the fruit;

c) screening out solid components above a predetermined dimension; and

d) separating by centrifugation a fruit serum from a solid material thus obtained and retaining said chromoplast particles with said solid material,

wherein said process is carried out under conditions providing said chromoplast particles containing crystalline lycopene in said solid material ~~such that the chromoplasts are substantially intact,~~ thereby obtaining a color concentrate comprising ~~the~~ said color-imparting agent~~;~~.

wherein the coloring material comprises from 500 to 3000 ppm of lycopene and wherein the coloring material has a soluble solids concentration below 5° Bx.

10. (Amended) A process according to claim 8, further comprising water-washing the color concentrate, ~~to remove water-soluble flavors.~~

12. (Amended) A process according to claim 10, ~~wherein processing comprises~~ comprising at least one preservation technique selected from the group consisting of ~~any one of a number of preservation techniques, such as aseptic packaging, freezing, canning and/or dehydrating, optionally alone or with the addition of a suitable food preservatives.~~

24. (Twice Amended) A process for coloring a food product which comprises:

a) cleaning and breaking tomatoes which comprise chromoplasts containing lycopene in the amount of at least 120 ppm;

b) screening out solid components therefrom of a predetermined size; and

c) separating a serum from a screened tomato solid material by centrifugation and retaining said chromoplasts with said tomato solid material,

wherein said process is carried out under conditions providing said chromoplast particles containing crystalline lycopene in said tomato solid material ~~such that the chromoplasts are substantially intact,~~

thereby to obtain a color concentrate comprising said chromoplasts containing crystalline lycopene in a concentration from 500 to 3000 ppm_L and

d) introducing said concentrate into said food ~~products~~ product.

25. (Amended) A process according to Claim 24 wherein unless said products are not tomato products, further comprising washing the color concentrate ~~to remove the tomato~~ flavor.

41. (Amended) In a food product or a health-promoting and health-maintaining consumable product comprising a lycopene additive of lycopene molecules as a food colorant or as a nutraceutical, the improvement wherein

said lycopene molecules are in crystalline form encapsulated in chromoplasts, ~~and wherein said chromoplasts are substantially intact~~

said chromoplasts are particles separated from a fruit which contained them,

the lycopene additive comprising from 500 to 3,000 ppm of said chromoplasts encapsulating said lycopene molecules, and

wherein said lycopene additive has a soluble solids concentration below 5° Bx.